

COVID-19 Vaccine Webinar for Healthcare Providers

Update on COVID-19 Vaccines Across the Age Span

July 1, 2022

Laura Conklin, MD and Lyndsey Hoyt, MPH Division of Epidemiology New York State Department of Health

Webinar Agenda

- COVID-19 epidemiology updates
- General vaccine information and updated recommendations
- Clinical considerations for special groups
- Talking to children and parents about the COVID-19 vaccine
- Training resources for vaccine delivery in pediatric patients
- COVID-19 vaccine provider requirements
- Additional resources
- Where to direct questions

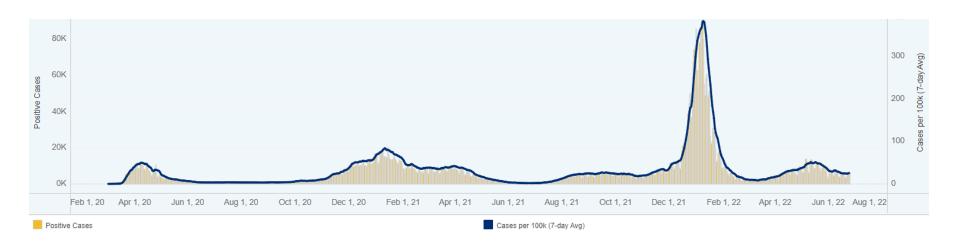
The information in this document is current as of June 28 and is subject to change as guidance is updated!



Updates on COVID-19 Epidemiology

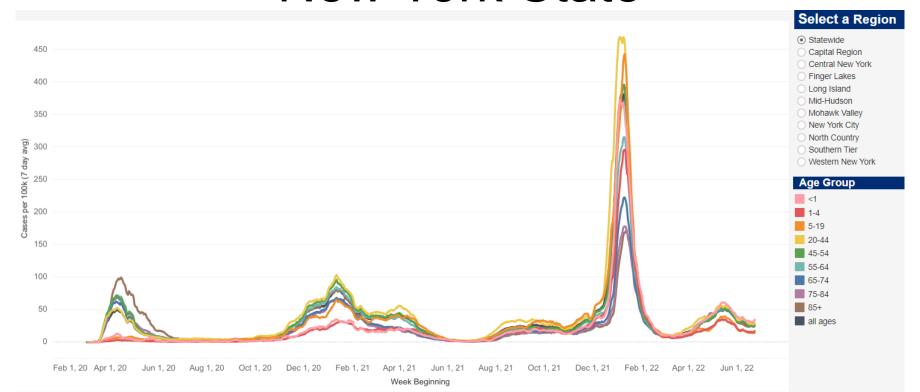


New York State Timeline Reported COVID-19 Cases

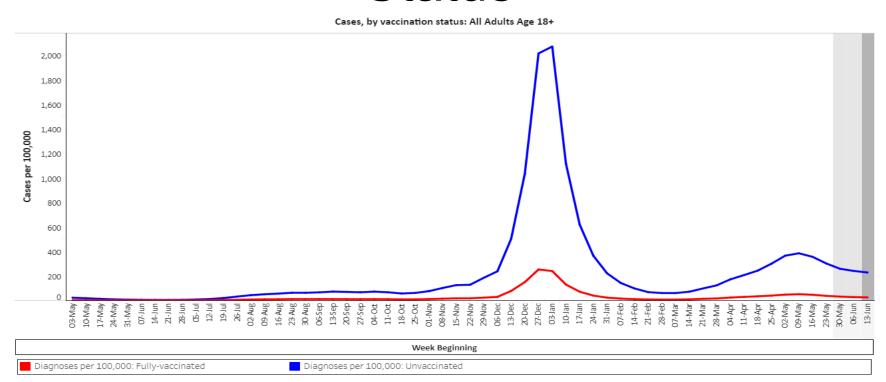




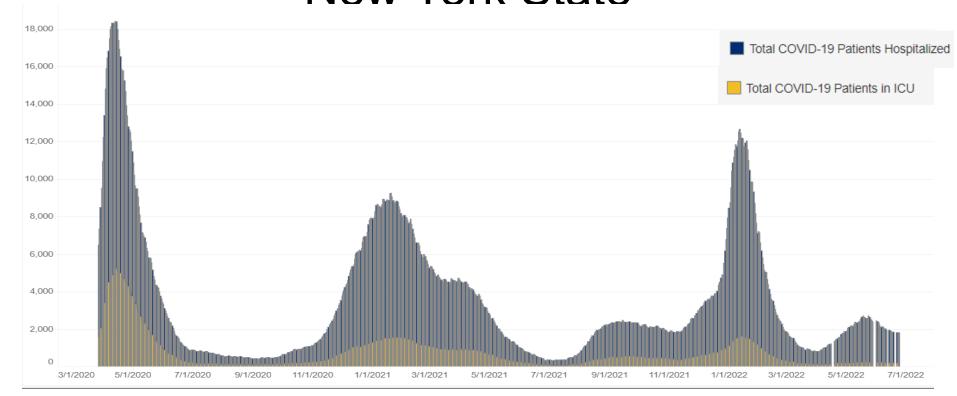
COVID-19 Cases by Age Group, New York State



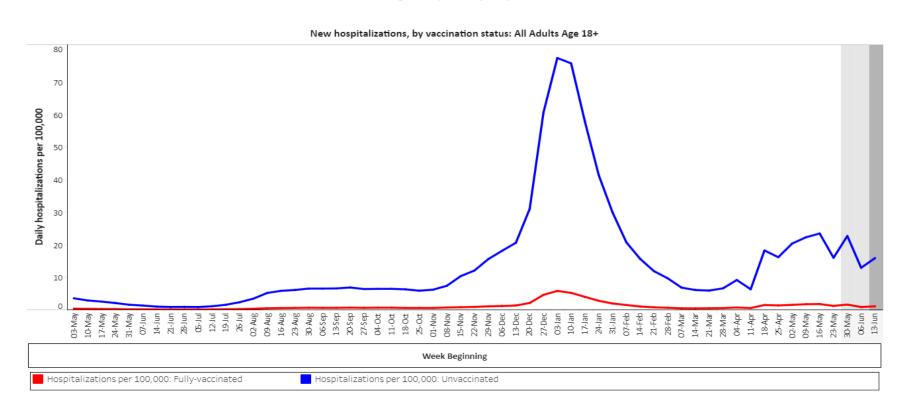
COVID-19 Cases and Vaccination Status



Prevalent COVID-19 Hospitalizations in New York State

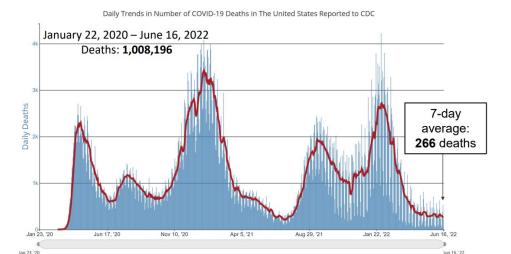


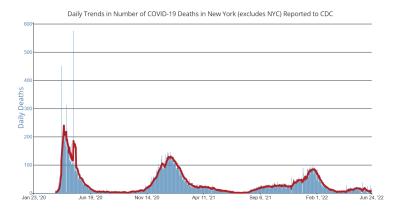
COVID-19 Hospitalization and Vaccine Status

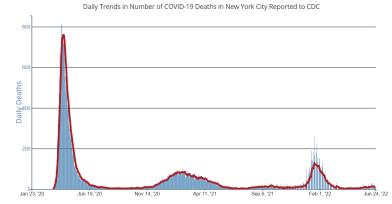


COVID-19 Mortality: US and New York

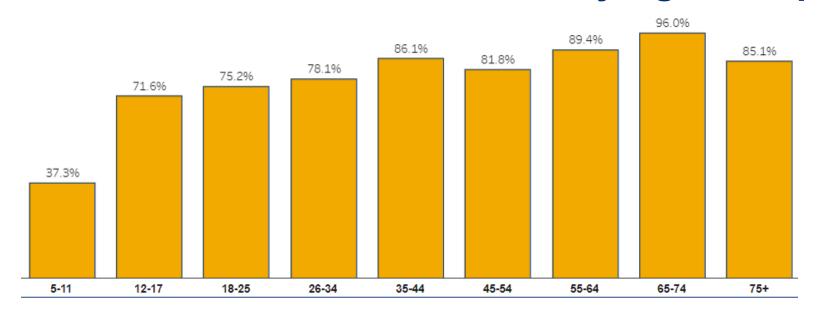
Daily Trends in Number of COVID-19 Deaths, United States







Percent of People in New York State with COMPLETE Vaccination Series, by Age Group





Call to Action

- Trusted health care providers are uniquely positioned to discuss and provide COVID-19 vaccination with patients and families.
- Talk with your patients and parents about the importance of getting vaccinated.

Ways you can do your part:

- Enroll in the NYS COVID-19 Vaccination Program
 - You do NOT need an ultra-low temperature freezer
- Discuss and strongly recommend vaccination to your patients and family members who have not yet been vaccinated
- Facilitate vaccination appointment scheduling, if you cannot administer the vaccine directly

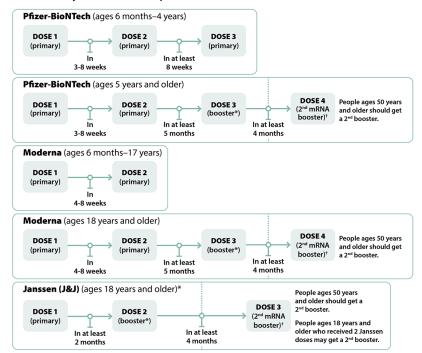


COVID-19 Vaccine General Information and Updated CDC Recommendations



Current Vaccine Recommendations

COVID-19 Vaccination Schedule for People who are **NOT** Moderately or Severely Immunocompromised



^{*}Age-appropriate mRNA COVID-19 vaccines are preferred over Janssen COVID-19 Vaccine for primary and booster vaccination. Janssen COVID-19 Vaccine should only be used in limited situations. See: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#considerations-Janssen

**As of June 24, 2022 Moderna COVID-19 vaccine has been authorized by FDA and recommended by CDC for use in children ages 6 months – 17 years

Link:

https://www.cdc.gov/vaccines/covi d-19/images/COVID19vaccination-schedule-mostpeople.png



^{†2}nd booster dose for some groups

Vaccine Efficacy of mRNA vaccines in young children

- Pfizer BioNTech (3ug dose, 6m-4 years)
 - Phase 2/3 trial showed similar immune response to 16-25yo population
 - Estimated vaccine efficacy against symptomatic lab-confirmed SARS-CoV-2 infection: ~ 80%
 - Well-tolerated; no new safety signals
- Moderna (6m-5 years)
 - Estimated vaccine efficacy against symptomatic lab-confirmed SARS-CoV-2 infection:
 - 6 to 23 months ~51%
 - 2 to 5 years ~46%
 - Immunogenicity studies indicate likely high level of protection from severe illness
 - Well-tolerated; no new safety signals



Pfizer-BioNTech COVID-19 Vaccine Formulations

Description	Dilute Before Use	Do Not Dilute	Dilute Before Use	Dilute Before Use
Age Group	12 years and older ^{1,2}	12 years and older ³	5 through 11 years ⁴ ("Age 5y to <12y" on vial label)	6 months through 4 years ⁵ (See additional information in boxed maroon text below table)
Vial Cap Color	Purple	Gray	Orange	Maroon
Dose	30 mcg	30 mcg	10 mcg	3 mcg
Dose Volume	0.3 mL	0.3 mL	0.2 mL	0.2 mL
Amount of Diluent Needed per Vial*	1.8 mL	NO DILUTION	1.3 mL	2.2 mL
Doses per Vial	6 doses per vial (after dilution)	6 doses per vial	10 doses per vial (after dilution)	10 doses per vial (after dilution)

*ONLY use sterile 0.9% Sodium Chloride Injection, USP as the diluent. Do not use bacteriostatic 0.9% Sodium Chloride Injection or any other diluent. Information about Storage Conditions on next page.

References: 1. COMIRNATY® (COVID-19 Vaccine, mRNA). Prescribing Information. Pfizer and BioNTech;
December 16, 2021. 2. Pfizer-BioNTech COVID-19 Vaccine. Emergency Use Authorization Fact Sheet for Healthcare
Providers Administering Vaccine (Vaccination Providers) (12 years of age and older), DILUTE BEFORE USE, Purple Cap.
Pfizer and BioNTech; June 17, 2022. 3. Pfizer and BioNTech COVID-19 Vaccine. Emergency Use Authorization Fact Sheet
for Healthcare Providers Administering Vaccine (Vaccination Providers) (12 years of age and older), DD NOT DILUTE,
Gray Cap. Pfizer and BioNTech; June 17, 2022. 4. Pfizer-BioNTech COVID-19 Vaccine. Emergency Use Authorization
Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (5 through 11 years of age), DILUTE
BEFORE USE, Orange Cap. Pfizer and BioNTech; June 17, 2022. 5. Pfizer-BioNTech COVID-19 Vaccine. Emergency Use
Authorization Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) (6 months through 4
years of age), DILUTE BEFORE USE, Maroon Cap. Pfizer and BioNTech; June 17, 2022.

The vial labels may state "Age 2y to < 5y" or "Age 6m to < 5y" and carton labels may state "For age 2 years to < 5 years" or "For age 6 months to < 5 years."
Vials with either printed age range can be used for individuals 6 months through
4 years of age.



Moderna COVID-19 Vaccine Formulations



The Moderna COVID-19 Vaccine vial labeled "BOOSTER DOSES ONLY" is also authorized to provide Primary Series Doses (0.5 mL each) for individuals 6 through 11 years of age. Please see the Dear HCP Letter for more information.

On the horizon...





COVID-19 Vaccines: 6m - 4(or 5) yo without immunocompromise*

Info	Pfizer-BioNTech	Moderna
Age indication	6 months through 4 years**	6 months through 5 years
Total number of doses	3 doses	2 doses
Minimum Intervals	Dose 1-2: 3-8 weeks Dose 2-3: 8 weeks*	Dose 1-2: 4-8 weeks
Dose	3 micrograms/0.2mL	25 micrograms/0.25mL
Dilution	2.2 mL (diluent provided in ancillary kit)	Not required
Vial caps/labels	Maroon cap and vial labels with maroon border	Blue cap vial with vial labels with magenta border
Shipping	-80° C	-20° C
Storage after received	Up to 12 months from manufacture date at ultra-cold temperatures of -90°C to -60°C <i>OR</i> Up to 10 weeks at refrigerated temperatures of 2°C to 8°C (36°F to 46°F). NOTE: NO standard freezer storage is approved for this formulation.	Until expiration at standard freezer temperatures - 50°C to -15°C (-58°F to 5°F). Expiration dates found at https://eua.modernatx.com/covid19vaccine-eua/providers/vial-lookup OR Up to 30 days at refrigerated temperatures of 2°C to 8°C (36°F to 46°F)
Packaging configuration	10-dose vials	10-dose vials
Post-puncture	Use/discard within 12 hours**	Use/discard within 12 hours

^{*} As of June 24, 2022

^{**} information in EUA fact sheet supersedes information on Pfizer-BioNTech vial labels and cartons

COVID-19 Vaccines: 5 (or 6) to 11yo without immunocompromise *

Info	Pfizer-BioNTech	Moderna
Age indication	5 to 11 years	6 to 11 years
Total number of doses	3 doses	2 doses
Minimum Intervals	Dose 1-2: 3-8 weeks Dose 2-3: 5 months*	Dose 1-2: 4-8 weeks
Dose	10 micrograms/0.2mL	50 micrograms/0.5mL
Dilution	1.3 mL (diluent provided in ancillary kit)	Not required
Vial caps/labels	Orange cap and vial labels with orange border	Blue cap vial with vial labels with purple border
Shipping	-80° C	-20° C
Storage after received	Up to 12 months from manufacture date at ultra-cold temperatures of -90°C to -60°C OR Up to 10 weeks at refrigerated temperatures of 2°C to 8°C (36°F to 46°F). NOTE: NO standard freezer storage is approved for this formulation.	Until expiration at standard freezer temperatures - 50°C to -15°C (-58°F to 5°F). Expiration dates found at https://eua.modernatx.com/covid19vaccine-eua/providers/vial-lookup OR Up to 30 days at refrigerated temperatures of 2°C to 8°C (36°F to 46°F)
Packaging configuration	10-dose vials	5-dose vials
Post-puncture	Use/discard within 12 hours**	Use/discard within 12 hours

^{*} As of June 24, 2022 ** informatio

^{**} information in EUA fact sheet supersedes information on Pfizer-BioNTech vial labels and cartons

COVID-19 Vaccines ≥12yo *without* immunocompromise *

Info	Pfizer-BioNTech (GRAY CAP)	Moderna
Age indication	12+	12+
Total number of doses	3 doses 4 doses (over age 50)	2 doses 3 doses (≥18 yo); 4 doses (≥50 yo)
Minimum Interval	Dose 1-2: 3-8 weeks** Dose 2-3: 5 months Dose 3-4: 4 months (≥50 yo)	Dose 1-2: 4-8 weeks** Dose 2-3: 5 months (≥18 yo) Dose 3-4: 4 month (≥50 yo)
Dose	30 micrograms/0.3mL	50 micrograms/0.5mL
Dilution	Not required	Not required
Vial caps/labels	Gray cap and vial labels with gray border	Red cap with vial labels with blue border
Shipping	-80° C	-20° C
Storage after received	Up to 12 months from manufacture date at ultra-cold temperatures of -90°C to -60°C OR Up to 10 weeks at refrigerated temperatures of 2°C to 8°C (36°F to 46°F). NOTE: NO standard freezer storage is approved for this formulation.	Until expiration at standard freezer temperatures - 50°C to -15°C (-58°F to 5°F). Expiration dates found at https://eua.modernatx.com/covid19vaccine-eua/providers/vial-lookup OR Up to 30 days at refrigerated temperatures of 2°C to 8°C (36°F to 46°F)
Packaging configuration	6-dose vials	10-dose vials
Post-puncture	Use/discard within 12 hours	Use/discard within 12 hours

^{*} As of June 24, 2022 ** An 8-week interval between 1st and 2nd doses may reduce the risk of myocarditis/pericarditis particularly in males ages 12-39 years

EUA Fact Sheets

- EUA Fact Sheet for Vaccination Providers Pfizer Ages 12+ purple cap
- <u>EUA Fact Sheet for Vaccination Providers Pfizer Ages 12+ gray cap</u>
- EUA Fact Sheet for Vaccination Providers Pfizer Ages 5-11 orange cap
- EUA Fact Sheet for Vaccination Providers Pfizer Ages 6m-4y maroon cap
- EUA Fact Sheet for Vaccination Providers Moderna Ages 12+
- EUA Fact Sheet for Vaccination Providers Moderna Ages 6-11
- EUA Fact Sheet for Vaccination Providers Moderna Ages 6m-5y
- EUA Fact Sheet for Vaccination Providers Moderna 18+ booster



Clinical Considerations for Children <12 yrs

- Children should receive the <u>age-appropriate dosing regardless of</u> their weight
- Dosage should depend on the child's age at the day of vaccination, for each dose
 - Example: If a child is 4 at the time of dose #1 then turns 5 before dose #2, they should receive the 6m-4yo dosage for dose #1 and 5-11yo dosage for dose #2
 - However, the FDA EUA allows children who will turn from 4 to 5 years of age between doses to receive, for either dose, either the formulation for 6 m-4 years or the formulation for 5-11 years.
 - These are NOT considered vaccine administration errors and do not need to be reported to the Vaccine Adverse Event Reporting System (VAERS)



Potential Administration Errors

- Administration errors do occur!
- Report adverse events and administration errors to CDC through VAERS: https://vaers.hhs.gov/reportevent.html
- CDC recommendations regarding vaccine administration errors can be found here:

https://www.cdc.gov/vaccines/covid-19/clinicalconsiderations/interim-considerationsus.html#appendix-

c:~:text=Appendix%20C.%20Vaccine%20administration %20errors%20and%20deviations





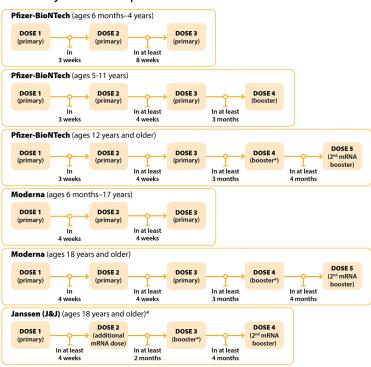
Clinical Considerations for Special Groups



Clinical Considerations: Immunocompromised

- Description of moderately to severely immunocompromising conditions on CDC website: link
- Primary series doses* authorized for children in this group:
 - Pfizer: 3-dose primary series
 - Moderna: 3-dose primary series
- Booster doses* authorized for children in this group:
 - Pfizer
 - 5-11 years: 1 booster
 - 12 years and older: 2 boosters
 - Moderna: 18 years and older: 2 boosters

COVID-19 Vaccination Schedule for People who **ARE** Moderately or Severely Immunocompromised



^{*}Age-appropriate mRNA COVID-19 vaccines are preferred over Janssen COVID-19 Vaccine for primary and booster vaccination, Janssen COVID-19 Vaccine should only be used in limited situations. See: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-ushtmileconsiderations-Janssen

nttps://www.cdc.gov/vaccines/covid-19/images/@VID19-vaccination-schedule-immunocompromised.png

^{*}Additional primary doses are dose administered to people who likely did not mount a protective immune response after initial vaccination. *Booster doses are administered to enhance or restore protection by the primary vaccination which might have waned over time.

Clinical Considerations: Prior COVID-19 infection

- COVID-19 vaccination should be given regardless of history of prior COVID-19 infection
 - Clinical trials and the COVID-19 vaccine experience to date have demonstrated the safety of mRNA COVID-19 vaccines in people with a history of prior COVID-19 infection
 - Serologic testing for prior COVID-19 infection is <u>not</u> recommended prior to vaccination
 - Vaccination should be deferred in persons <u>currently</u> ill with COVID-19 until they have recovered and met criteria to end isolation
 - Note: CDC guidelines updated to include an option of 3-month deferral
- If the patient has received passive antibody products:
 - Can be vaccinated at any time
 - COVID-19 vaccination does not need to be delayed following receipt of monoclonal antibodies or convalescent plasma

Clinical Considerations: Multisystem Inflammatory Syndrome in Children (MIS-C)

- Rare syndrome reported w/in 4 weeks of SARS-CoV-2 infection
 - 1 in 3000 children with lab-confirmed COVID-19
 - Presentation: fever, laboratory evidence of inflammation, and evidence of clinically severe illness requiring hospitalization, with multisystem (>2) organ involvement
- The benefits of COVID-19 vaccination are likely to outweigh the potential and known risks in children with a history of MIS-C before COVID vaccination if:
 - Clinical recovery has been achieved, including a return to normal cardiac function; and
 - o It has been ≥ 90 days since diagnosis of MIS-C; and
 - They are in an area of high or substantial community transmission of SARS-CoV-2, or otherwise have an increased risk for SARS-CoV-2 exposure and transmission
 - Persons with a history of MIS-C onset after a prior COVID-19 vaccination should discuss subsequent doses with their doctor

Multisystem Inflammatory Syndrome in Children (MIS-C) Resources

Information about MIS-C in NYS:

https://coronavirus.health.ny.gov/multisysteminflammatory-syndrome-children-mis-c

Resources for parents:

https://www.cdc.gov/mis/mis-c.html

AAP resources on MIS-C

https://www.aap.org/en/pages/2019-novelcoronavirus-covid-19-infections/clinicalguidance/multisystem-inflammatory-syndrome-inchildren-mis-c-interim-guidance/

How to Recognize

Multisystem Inflammatory Syndrome in Children (MIS-C)

A Delayed Immune Response Related to COVID-19

Children, adolescents, or young adults who develop certain symptoms after having COVID-19 might have MIS-C. They should see a doctor if they had COVID-19, or have been in close contact with someone who had COVID-19, within the past 6 weeks and now have the following:

Ongoin



PLUS more than one of the following:







Diarrhea



Vomiting







Eyes



Dizziness or Lightheadedness

Go to the nearest hospital Emergency Room if your child is showing



Clinical Considerations: Co-administration

- COVID-19 vaccines may be administered without regard to timing of other vaccines*
 - Includes simultaneous administration of COVID-19 vaccine and other vaccines on the same day
 - If multiple vaccines are administered at a single visit, administer each injection in a different injection site.
- Best practices for multiple injections
 - Label each syringe with the name and the dosage (amount) of the vaccine, lot number, initials of the preparer, and exact beyond-use time, if applicable.
 - Separate injection sites by 1 inch or more, if possible.
 - Administer the COVID-19 vaccine and vaccines that may be more likely to cause a local reaction in different limbs, if possible.



Talking to Parents and Children about the COVID-19 Vaccine

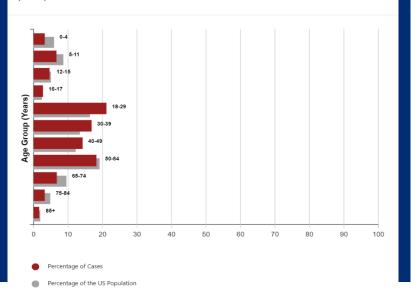




COVID-19 Disease, by Age Group

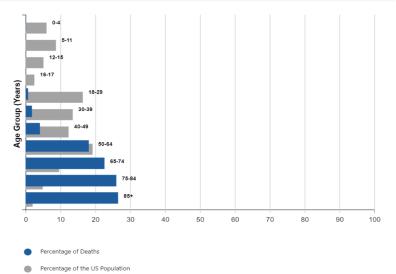
Cases by Age Group:

Data from 76,365,726 cases. Age group was available for 75,604,080 (99%) cases.



Deaths by Age Group:

Data from 860,267 deaths. Age group was available for 859,477 (99%) deaths.





Source: https://covid.cdc.gov/covid-data-tracker/#demographics

Benefits: mRNA COVID-19 vaccine, 6m-4yo

- Young children are at risk of severe COVID-19
 - >1400 COVID-19 hospitalizations in this age group from March 2020 January 2022
 - Children with underlying medical conditions at highest risk*
 - Multisystem inflammatory syndrome in children (MIS-C)
 - Post-COVID conditions have been reported in children
 - Children <18 years who have had COVID-19 are up to 2.5 times more likely to be newly diagnosed with diabetes 30 days or more after infection
- Secondary transmission in household, childcare and school settings
 - Leads to missed school/childcare for themselves and classmates, missed work for parents
 - Potential for transmission to high-risk individuals and siblings <6 months of age
 - Mental health benefits of being a part of your community and child development benefits

^{*}including genetic/neurologic/metabolic conditions, congenital heart disease, obesity, diabetes, asthma, chronic lung disease, sickle cel disease, immunosuppression

Safety of mRNA COVID-19 Vaccines

- Key points when talking to parents
 - COVID-19 mRNA vaccines were developed using science that has been around for decades.
 - COVID-19 vaccines are safe much safer than getting COVID-19.
 - COVID-19 vaccines are effective at preventing severe COVID-19 illness and limiting the spread of virus that cause it.
- Based on what we know from phase 2/3 trials, and experience in 5-11 yo group:
 - Common adverse events
 - Local symptoms: Pain, swelling, and redness at injection site
 - General symptoms: fever, fatigue, headache, chills, myalgia, arthralgia, lymphadenopathy
 - <u>Similar to (or milder than)</u> those in older children and adults
 - Rare adverse events: anaphylaxis, myocarditis/pericarditis



Safety considerations: Anaphylaxis

- 5 anaphylaxis cases per one million COVID-19 vaccine administered
 - People with history of severe allergic reaction to COVID-19 vaccine or a component are at highest risk
- Most common after first dose and within 30 minutes of vaccination
- Management in infants and young children (require standing orders)
 - Patients <7.5kg (16.5lbs): Autoinjectors not authorized; use aqueous epi
 - Patients 7.5-14kg (16.5-32lbs): Autoinjector (e.g., AUVI-q) 0.1mg
 - Patients 15-29kg (33-65lbs): Autoinjector (e.g., EpiPen Jr) 0.15mg
 - Patients >30kg (66lbs): Autoinjector (e.g., EpiPen) 0.3mg



Appendix B: Triage of people with a history of allergies or allergic reactions

CONTRAINDICATION TO COVID-19 VACCINATION	PRECAUTION TO COVID-19 VACCINATION	MAY PROCEED WITH COVID-19 VACCINATION
Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of a COVID-19 vaccine ^{1,2} Known (diagnosed) allergy to a component of a COVID-19 vaccine ¹	 Among people without a contraindication, a history of: Any immediate allergic reaction³ to other vaccines (non-COVID-19) or injectable therapies⁴ Non-severe, immediate (onset <4 hours) allergic reaction² after a previous dose of COVID-19 vaccine⁵ Note: people with a contraindication to mRNA COVID-19 vaccines have a precaution to Janssen COVID-19 Vaccine, and vice versa⁵ 	Among people without a contraindication or precaution, a history of: • Allergy (including anaphylaxis) to oral medications (including the oral equivalent of an injectable medication) • History of food, pet, insect, venom, environmental, latex, etc., allergies, including anaphylaxis • Family history of allergies
Actions: Do not vaccinate Consider referral to allergistimmunologist Consider other vaccine alternative if age appropriate ^{1,5}	Actions: Risk assessment 30-minute observation period if vaccinated (see footnotes 5 and 6 for information on vaccination setting) Consider referral to allergistimmunologist	Actions: 30-minute observation period: people with history of anaphylaxis (due to any cause) 15-minute observation period: all other people

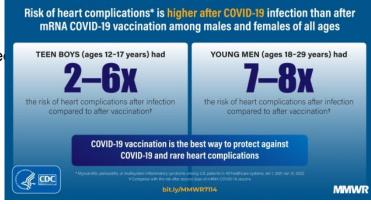
Link:

https://www.cdc.gov/vacc ines/covid-19/clinicalconsiderations/interimconsiderationsus.html#appendix-e



Safety considerations: Myocarditis/Pericarditis

- Inflammation in/around heart muscle
- Highest risk: males 12-29 yo, 2nd dose, <1 week of vaccination
 - 5-11 years: 20 verified reports after 18,405,693 doses administere
 - 12-15 years: 348 verified reports after 23,231,892 doses administered
 - 16-17 years: 297 verified reports after 12,653,820 doses administered
- The risk after vaccination is lower than the risk associated with COVID-19 disease
- Most patients with myocarditis after mRNA COVID-19 vaccination have been hospitalized for short periods, with most achieving resolution of acute symptoms
- Extending the interval between the first and second mRNA vaccine dose to 8 weeks might reduce the risk.





After Vaccination: Talking to Parents

- Positive reinforcement for parents
 - o Praise them for getting their child vaccinated!
- Getting eligible children vaccinated against COVID-19 can help keep them:
 - From getting COVID-19
 - From getting really sick if they do get COVID-19
 - Safer when they attend school or daycare
 - More safely participating in sports, playdates, and other group activities.
- Remind them to make a note of their child's next vaccine appointment to make sure they are fully vaccinated and fully protected
- Remind them of the most common side effects after getting vaccinated







Addressing Vaccine Hesitancy



- Dedicated communications effort to promote vaccine confidence and quickly address misinformation that may spread on social media and in other media forms
 - <u>Frequently Asked Questions</u> Answers to common questions about the COVID-19 vaccine.
 - Get the Vax Facts Campaign to counter misinformation and disinformation with downloadable toolkits
- CDC resources and redesigned websites
 - Myths and FACTS about COVID-19 vaccines https://www.cdc.gov/coronavirus/2019-ncov/vaccines/facts.html
 - <u>12 COVID-19 Vaccination Strategies for Your Community</u>
 - How to Address COVID-19 Vaccine Misinformation



V-SAFE program

Promoting v-safe in Practice – We Need Your Help!

- How immunization programs can promote v-safe:
 - Encourage discussion of v-safe at the vaccination visit
 - For youngest children, ideally prior to vaccination
 - Ask sites to display posters of v-safe
 - Ask sites to provide v-safe information sheet to patients



https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe/printresources.html





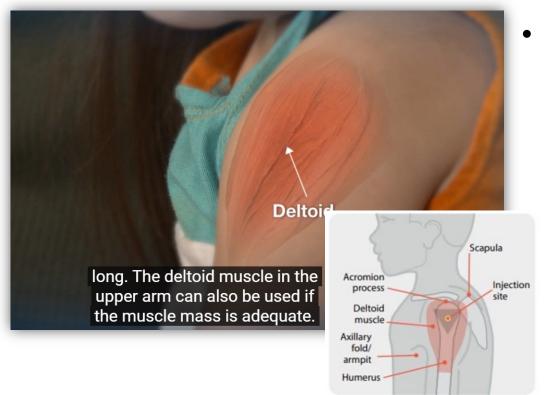
Training Resources for Staff or Clinics New to Pediatric Vaccination



Overview of Vaccine Administration in infants and young children

	Infants 6-12m	Children 1-2 years	Children 3-4 years	
Needle gauge and length	1"	5/8"-1" (arm) 1"-1.25" (thigh)	5/8"-1" (arm) 1"-1.25" (thigh)	
Injection site	Thigh	Thigh (preferred) Arm (if adequate muscle mass)	Arm (preferred) Thigh (alternate option)	
Restraint technique(s)	Caregiver embrace (side)	Caregiver embrace (side) Straddle restraint	Straddle restraint Caregiver embrace (side or front)	
Useful distractions	 Distract and comfort Cuddle, Sing, or talk softly. Comfort with a favorite toy, book or blanket. Hold your child firmly on your lap, whenever possible. Breast feeding, bottle, pacifier 	 Distract with book, phone, stories, or interesting things in the room Support your child if he or she cries. Never scold a child for not "being brave." Breast feeding, bottle, pacifier 	 Distract with book, phone, stories, or interesting things in the room Support your child if he or she cries. Never scold a child for not "being brave." Count or "blow out" imaginary candles. 	

CDC Videos for IM injections for Children



"Intramuscular (IM)
Injection: Supplies
(Children Birth Through 18
years of Age)"

"Intramuscular (IM)
Injection: Sites"
5:10 minutes



Resources for Pediatric Vaccination

Positioning the pediatric patient:

- You Call The Shots Vaccine
 Administration:Intramuscular (IM) Injection Infants 11
 months of age and younger (cdc.gov)
- https://www.health.state.mn.us/diseases/coronavirus/v accine/comforthold.pdf
- https://www.cdc.gov/vaccines/parents/visit/holdsfactsheet.html
- How to hold your child during a vaccination (state.mn.us)

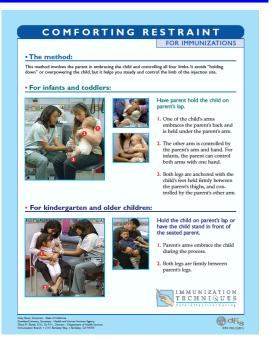






CDC Videos: Comfort & Restraint Techniques

 "Comfort and Restraint Techniques"







Vaccinating in Special Situations

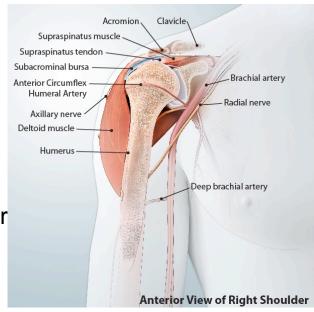
Vaccinating kids with disabilities

- https://www.cdc.gov/vaccines/covid-19/planning/children/disabilities.html
- https://www.cdc.gov/childrensmentalhealth/feature s/needle-fears-and-phobia.html
- https://www.cdc.gov/ncbddd/humandevelopment/C OVID-19-Materials-for-People-with-IDD.html
- https://www.cdc.gov/coronavirus/2019ncov/vaccines/children-teens-disabilities.html



What to avoid

- Shoulder injury related to vaccination administration (SIRVA)
 - Unintentional injection of vaccination into tissues/structures lying underneath the deltoid muscle
 - Manifests as shoulder pain and limited motion after administration of vaccine
 - Musculoskeletal injury (not neurological)
 - Reportable to VAERS





Example Check List for Training New Staff on Pediatric Vaccination

- ✓ Preparing the child and guardian for the vaccine
- ✓ Reviewing protocols: screening & consent
- ✓ Avoiding errors/dispensing
- ✓ Dispensing supplies: needle size etc.
- ✓ Talking to parents
- ✓ Preparing the workspace
- ✓ Pediatric restraint techniques
- ✓ Positioning and anatomic landmarks
- ✓ Shoulder Injury from Vaccine (SIRVA)
- ✓ Mock vaccination routine
- ✓ After vaccine comfort
- ✓ Waiting time
- √ Reporting errors and adverse events



COVID-19 Vaccine Provider Requirements



COVID-19 Vaccination Program Enrollment

- Provider locations must be enrolled in the COVID-19 vaccination program with a signed CDC Provider Agreement in order to receive or administer COVID-19 vaccine.
- Locations in New York State outside of the 5 New York City boroughs enroll in the NYS COVID-19 Vaccination Program via an application tool in the Health Commerce System (HCS).
- Requests for vaccine and reporting of doses administered is done through the New York State Immunization Information System (NYSIIS).
- New York City locations enroll via the New York City Department of Health and Mental Hygiene's Citywide Immunization Registry (CIR).



Enrollment Process For Locations <u>Outside</u> NYC

Step 1: Complete the online COVID-19 Vaccine Program Provider Enrollment application located in the Health Commerce System (HCS). There are a set of <u>resource documents</u> to assist you.

The application includes two sections:

Section A: Provider Requirements and Legal Agreement specifies the conditions of participation and must be filled out for the organization (i.e., network, health system, or medical group).

Section B: Program Provider Profile Form must be filled out for every vaccination provider location receiving and administering COVID-19 vaccine.

Step 2: Ensure the appropriate individuals have access to the New York State Immunization Information System (NYSIIS).

New users must complete two <u>NYSIIS Trainings</u> in order to obtain NYSIIS accounts.

- Standard User Training, approximately 45 minutes
- Administrative User Training, approximately 20 minutes

NYSIIS is used to submit requests for vaccine, manage vaccine inventory and report doses administered.

Step 3: Sign and return a "Memorandum of Understanding (MOU) for the COVID-19 Vaccination Program" to demonstrate commitment to complying with New York State's directives regarding the COVID-19 Vaccination Program.

The MOU will be emailed to you after you submit an application in the HCS.

The MOU is required in addition to the online enrollment application.

Enrollment Process For Locations In NYC

Step 1: Register your facility in the CIR to obtain a CIR facility code. Go to the <u>online registration page</u> to register your facility for the first time or to update an existing registration if your facility has not reported to the CIR in over a year. You will need the National Provider Identifier (NPI) number and NYS medical license number of the provider-in-charge to complete the registration.

Step 2: Create a CIR Online Registry (OR) account. To do so, you must complete the two forms listed below, then scan and email them to cir-reset@health.nyc.gov.

- Security Administrator (User Manager) Confidentiality Statement for Online Access and Acceptable Use Protocol (PDF)
- Security Administrator (User Manager) User ID/Password Request Form (Facilities) (PDF)

Step 3: After you have a facility code and OR account set up, you will be able to access the Vaccination Provider Agreement System (VPAS) from inside the OR. Paper forms are not accepted. NYC is accepting only online enrollments. This agreement is for enrollment in the COVID-19 Vaccination Program; it is not a vaccine order.

Once your VPAS agreement has been approved, you will be notified to order vaccine. Please be sure to complete both Parts A and B in VPAS. Part B will appear as a link in the upper left of the screen after completing Part A. Instructions are attached. For assistance with VPAS, email nycimmunize@health.nyc.gov.

For full instructions, please visit:

https://www1.nyc.gov/assets/doh/downloads/pdf/covid/providers/covid-19-vaccine-enroll-order-report.pdf



COVID-19 Vaccine Ordering

- Providers enrolled in New York State (outside New York City) place orders in NYSIIS (NYC providers order through CIR following NYCDOHMH instructions)
 - COVID-19 vaccine orders should always be placed separately from Vaccines for Children (VFC), Vaccines for Adults (VFA) and flu orders
 - Can be placed any day of the week
 - There is no limit to frequency of COVID-19 vaccine orders. NYSDOH recommends ordering enough doses for a 3-week supply (considering administration and current inventory) to reduce the risk of wastage due to expiration
 - Orders that are approved in NYSIIS ship from Pfizer or McKesson (Moderna and J&J vaccine) and typically deliver within 3-5 business days. Shipment notification emails are sent from Pfizer or McKesson to the primary vaccine coordinator.



Minimum Ordering Quantities (as of 6/2022)

Product	Minimum Order Qty	Packaging	
Pfizer 12+ (gray cap)	300 doses	2 boxes; 25 6-dose vials	
Pfizer 5-11 (orange cap)	100 doses	1 box; 10 10-dose vials	
Pfizer 6m-4y (maroon cap)	100 doses	1 box; 10 10-dose vials	
Janssen (J&J)	100 doses	2 boxes; 10 5-dose vials	
Moderna 12+ (red cap)	100 doses	1 box; 10 10-dose vials	
Moderna 6-11 primary/18+ booster (blue cap/purple label)	100 doses	2 boxes; 10 5-dose vials	
Moderna 6m-5y (blue cap/magenta label)	100 doses	1 box; 10 10-dose vials	

The amounts are set by CDC based upon contract between CDC Department of Health and manufacturer. NYS does not control minimum order quantities.

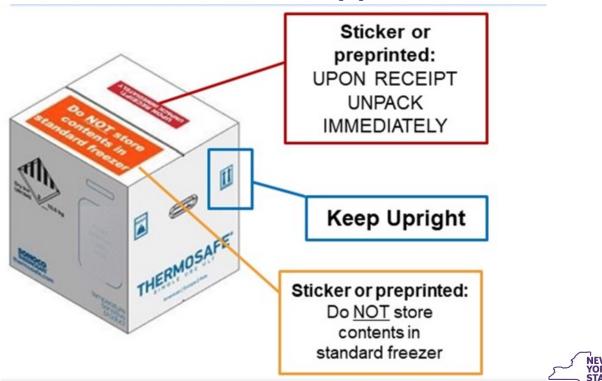
Responsible Wastage

- Providers should "take every opportunity to vaccinate every eligible person."
- As more vaccination opportunities are created, the likelihood of leaving unused doses in a vial may increase.
 - Once a vial of Moderna or Pfizer vaccine is diluted it must be used within 12 hours per the EUA. Any doses not administered within that time period must be reported as Wastage (see <u>Wastage Reporting Guidance</u>).
 - While enrolled providers must continue to follow best practices to use every dose possible, it should not be at the expense of missing an opportunity to vaccinate every eligible person when they are ready to get vaccinated.



Department of Health

Pfizer-BioNTech COVID-19 Vaccine Product Packaging - Thermal Shipper



Storage and Handling – Pfizer Formulations

Storage Conditions

Description	Dilute Before Use	Do Not Dilute	Dilute Before Use	Dilute Before Use
Vial Cap Color	Purple	Gray	Orange	Maroon
Ultra-Low-Temperature (ULT) Freezer [-90 °C to -60 °C (-130 °F to -76 °F)]	12 months*	12 months†	12 months†	12 months†
Freezer [-25 °C to -15 °C (-13 °F to 5 °F)]	2 weeks	DO NOT STORE	DO NOT STORE	DO NOT STORE
Refrigerator [2°C to 8°C (35°F to 46°F)]	1 month	10 weeks	10 weeks	10 weeks
Room Temperature [8 °C to 25 °C (46 °F to 77 °F)]	2 hours prior to dilution (including any thaw time)	12 hours prior to first puncture (including any thaw time)	12 hours prior to dilution (including any thaw time)	12 hours prior to dilution (including any thaw time)
After First Puncture [2 °C to 25 °C (35 °F to 77 °F)]	Discard after 6 hours	Discard after 12 hours	Discard after 12 hours	Discard after 12 hours‡



Storage and Handling – Pfizer Formulations



During storage, minimize exposure to room light. Avoid exposure to direct sunlight and ultraviolet light



Vials are glass and should be handled with care



Vials should always remain upright in cartons during storage



Do not touch frozen vials until there is a need to remove them from the carton for use or transfer



Product should be retained in the original vial cartons until ready for use



Protective gloves allowing manual dexterity should be worn while handling frozen vials



Storage and Handling – ALL Moderna Formulations

Frozen Storage

All Moderna COVID-19 Vaccine Presentations can be stored and handled in a consistent way and can be stored frozen until expiration date*

-50°C to -15°C (-58°F to 5°F)

During storage, minimize exposure to room light, and avoid exposure to direct sunlight and ultraviolet light.

For more information refer to the Fact Sheets for Healthcare Providers.

*Confirm vaccine expiration date by looking up the lot number at eua.modernatx.com/covid19vaccine-eua.



5.5 mL vials for Primary Series doses (for ages 12+) or Booster Doses (for ages 18+)



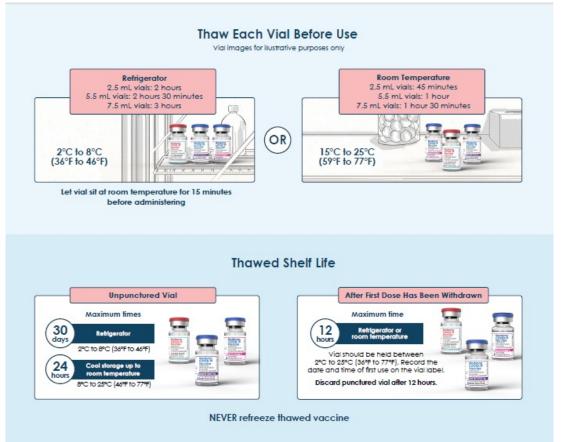
2.5 mL vials for Booster Doses only (for ages 18+) or Primary Series doses (for ages 6-11)



for Primary Series doses (for ages 6 months-5 years)



Storage and Handling – ALL Moderna Formulations





Beyond Use Dates (BUD)

- A shortened calculated use date that applies to certain instances:
 - When Pfizer vaccine is moved to refrigerator: 10-week BUD
 - When Modern vaccine is moved to refrigerator: 30-day BUD
 - When the vial is punctured:
 - Pfizer (gray, orange, and maroon cap) and Moderna (all formulations): 12 hours
 - J&J: 6 hours refrigerated or 2 hours room temperature
- The BUD replaces the manufacturer's expiration date and should be noted on the label along with the initials of the person making the calculation. Label the carton/vials with BUD at the time you remove from ULT/freezer!
 - Pfizer Gray Cap BUD Tracking Labels
 - Pfizer Orange Cap BUD Tracking Labels
 Pfizer Maroon Cap BUD Tracking Labels
 - Moderna (red cap) BUD Tracking Labels
 Moderna PED 6m-5y BUD Tracking Labels
- The BUD must never exceed the expiration date



Temperature Monitoring Requirements

- Each vaccine storage unit <u>MUST</u> have a digital data logger.
 - Detachable probe that best reflects vaccine temperature
 - Records temperatures at preset intervals, at least every 30 minutes
 - Temperature data can be either downloaded to a computer or retrieved from a website
 - Other features preferred:
 - Alarm for out-of-range temperatures
 - Low-battery indicator
 - Current, minimum and maximum temperature display
- Most freezer DDLs don't measure cold enough for ULT units (glycol probes will freeze at -59 C). Use a DDL with an air probe or probe designed specifically for ULT
- Must have a current and valid certificate of calibration testing to uncertainty of +/-0.5° C (+/-1° F)

Temperature Excursions

- Any time outside of recommended storage and handling conditions is considered a temperature excursion
- Label vaccines DO NOT USE and call manufacturer for determination on viability
- All excursions must be reported on the <u>New York State COVID-19</u>
 <u>Vaccination Program Temperature Excursion Report</u> and submitted to <u>vaccinetempexcursion@health.ny.gov</u>
 - Send data logs with tables and graphs with the Excursion Report



COVID-19 Vaccine Storage and Handling Resources

Pfizer COVID-19 vaccines

Storage and handling: https://www.cdc.gov/vaccines/covid-19/info-by-product/pfizer/storage.html

Excursion contact: 800-438-1985

Moderna COVID-19 vaccines

Storage and handling: https://www.cdc.gov/vaccines/covid-19/info-by-product/moderna/storage.html

Excursion contact: 866-MODERNA or excursions@modernatx.com; Excursion web tool: https://tools.modernamedinfo.com/excursion/

<u>Janssen</u>

Storage summary: https://www.cdc.gov/vaccines/covid-19/info-by-product/janssen/downloads/janssen-storage-handling-

summary.pdf

Excursion contact: 800-JANSSEN; Excursion web tool: https://www.janssenmd.com/janssen-covid19-vaccine/interactive-

content/stability-information

CDC Storage and Handling Toolkit: https://www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf

COVID-19 Vaccine Transport Guidance and Tracking Sheet: https://coronavirus.health.ny.gov/new-york-state-covid-19-

vaccine-program-guidance-vaccine-transport

^{*}Excursion web tools are for single excursions only. Must call for any subsequent excursions.

Reporting

- Entering vaccination data into NYSIIS or CIR (NYC) in an accurate and timely fashion is critical and required per the Provider Agreement.
- Providers are responsible for fixing any data entry errors identified.
- The Excelsior Pass verifies requests for passes against information entered into NYSIIS and CIR.
 - If data entered into NYSIIS or CIR is incorrect or incomplete because identity cannot be confirmed, fields are missing, or dates do not show they are fully vaccinated – the person cannot get a pass.



Additional Resources



Vaccine Finder.org

- Direct patients to find the appropriate vaccine type for age
- Provider Support: COVID-19 Administration Reporting Systems (CARS) Help Desk
 - Available M-F, 8am 8pm ET
 - CARS_HelpDesk@cdc.gov
 - 1-833-748-1979



Vaccines.gov: New vaccines listed in search



Training Documentation and Materials:

https://vaccine-resources.gitbook.io/vaccines.gov-provider-resources/



New York State Resources

- For FAQs, NYS Vaccine Tracker, and more information:
 - Covid19Vaccine.health.ny.gov
- For all New York State guidance regarding COVID-19 vaccination:
 - https://coronavirus.health.ny.gov/covid-19-vaccine-information-providers
- New York State COVID-19 Vaccine Hotline
 - 1-833-NYS-4-VAX (1-833-697-4829)
 - The COVID-19 Vaccine Hotline is open 9AM 6PM, Monday-Friday



Resources

- CDC Vaccine trainings for health care providers and vaccinators:
 - https://www.cdc.gov/vaccines/covid-19/training-education/index.html
 - https://www2.cdc.gov/vaccines/ed/covid19/index.asp
- ACIP general resources: ACIP's General Best Practice Guidelines for Immunization:
 - https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html
- Pfizer medical trainings
 - https://www.pfizermedicalinformation.com/en-us/medicalupdates



Resources

- VAERS reporting: <u>Vaccine Adverse Event Reporting System (VAERS)</u> (hhs.gov)
- Immunization Action Committee:
 - https://www.immunize.org/askexperts/experts cov.asp
 - https://www.immunize.org/vax-and-covid-19/
 - https://www.immunize.org/
 - https://www.immunize.org/dvd/
 - https://www.immunize.org/catg.d/p2005.pdf



Public Education (links to many educational resources)

 Dedicated communications effort to promote vaccine confidence and quickly address misinformation that may spread on social media and in other media forms

<u>Frequently Asked Questions</u> - Answers to common questions about the COVID-19 vaccine.

Get the Vax Facts - Campaign to counter misinformation and disinformation with downloadable toolkits

- Myths and FACTS about COVID-19 vaccines
 https://www.cdc.gov/coronavirus/2019-ncov/vaccines/facts.html
- Strategies to address vaccine hesitancy
 - 12 COVID-19 Vaccination Strategies for Your Community
 - How to Address COVID-19 Vaccine Misinformation



Resources for addressing vaccine hesitancy relating to pregnancy and/or fertility

- Preliminary Findings of mRNA COVID-19 Vaccine Safety in Pregnant Persons
 https://www.nejm.org/doi/full/10.1056/NEJMoa2104983?query=featured_home
- COVID Vaccine Hesitancy: Boston Doctors Address Concerns Around Fertility, Pregnancy

https://www.nbcboston.com/news/local/covid-vaccine-hesitancy-boston-doctors-address-concerns-around-fertility-pregnancy/2330291/

 CDC: Information about COVID-19 Vaccines for People who are Pregnant or Breastfeeding

https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/pregnancy.html

 CDC: COVID-19 Factsheet | Pregnancy https://www.cdc.gov/coronavirus/2019-ncov/downloads/communication/COVID-19 Pregnancy.pdf



Resources for addressing vaccine hesitancy

- COVID-19 Vaccine Recipient Education (CDC)
 - https://www.cdc.gov/vaccines/covid-19/hcp/index.html
- From Concern to Confidence: How physicians can build trust in COVID-19 vaccines (De Beaumont Foundation)
 - https://debeaumont.org/wp-content/uploads/2021/04/doctors-vaccines.pdf
- Webinar: Successful COVID-19 Messaging in Rural Communities (Public Health Communications Collaborative)
 - https://publichealthcollaborative.org/resources/webinar-successful-covid-19-messaging-in-rural-communities/
- An Uncertain Public Encouraging Acceptance of COVID-19 Vaccines (NEJM Perspective)
 - https://www.nejm.org/doi/full/10.1056/NEJMp2100351



Resources for addressing vaccine hesitancy (continued)

- Physicians will play key role building trust in COVID-19 vaccine (American Medical Association)
 https://www.ama-assn.org/about/leadership/physicians-will-play-key-role-building-trust-covid-19-vaccine
- COVID-19 vaccine hesitancy: 10 tips for talking with patients (American Medical Association)
 https://www.ama-assn.org/delivering-care/public-health/covid-19-vaccine-hesitancy-10-tips-talking-patients
- Vaccine Hesitancy: An Evolving Public Health Threat (Commissioner's Medical Grand Rounds: June 13, 2019)

https://www.health.ny.gov/commissioner/grand_rounds/vaccine_hesitancy/

Kaiser Family Foundation Vaccine Monitoring Dashboard:
 https://www.kff.org/coronavirus-covid-19/dashboard/kff-covid-19-vaccine-monitor-dashboard/



Resources

Videos that can be played on site:

- https://www.youtube.com/watch?v=vhHpOXJE8Yk
- https://www.youtube.com/watch?v=b0B-aqOJ7vw

Big Bird gets his COVID vaccine: https://www.youtube.com/watch?v=Kvx0oCvMm8g

Rosita gets the COVID vaccine

https://www.cnn.com/videos/health/2021/11/05/sesamestreet-town-hall-childrens-covid-vaccine-gupta-hill-vpx.cnn

https://youtu.be/yPlhRUF2aXA

How do vaccines help babies fight infections? | How Vaccines Work - YouTube



Resources for Older Kids

- General resources for kids and COVID
 https://www.kidshealth.org.nz/resources-help-explain-covid-19-children
- Explaining covid to kids
 https://news.umich.edu/new-video-website-explain-coronavirus-for-kids/
- UNICEF video on talking to kids about the COVID vaccine https://www.unicef.org/coronavirus/how-to-talk-to-children-covid-vaccines
- Segment with Bill Nye The Science Guy https://www.youtube.com/watch?v=i9GpIDZlg5A
- From Boston's Children's Hospital https://www.youtube.com/watch?v=p7fDNWwWyBE



Questions?

Covid19Vaccine@health.ny.gov

You may continue directing questions to this address after the webinar has concluded.

